UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 9, 2021

SYNDAX PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37708**	**32-0162505**
(state or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Building D, Floor 3 **35 Gatehouse Drive** **Waltham, Massachusetts** **(Address of principal executive offices)**	**02451** **(Zip Code)**

Registrant's telephone number, including area code: (781) 419-1400

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	SNDX	The Nasdaq Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☑

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☑

Item 2.02. Results of Operations and Financial Condition.

On August 9, 2021, Syndax Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated August 9, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SYNDAX PHARMACEUTICALS, INC.

By: /s/ Briggs W. Morrison, M.D.
Briggs W. Morrison, M.D.
Chief Executive Officer

Dated: August 9, 2021

Syndax Pharmaceuticals Reports Second Quarter 2021 Financial Results and Provides Clinical and Business Update

- Intermediate doses selected for Phase 2 portion of AUGMENT-101 trial of SNDX-5613 in patients with genetically-defined acute leukemias; updated data from Phase 1 portion expected in 4Q21 –

- Syndax initiating frontline combination of SNDX-5613 with venetoclax and azacitidine in the Beat® AML Master Clinical Trial –

- Enrollment ongoing in global pivotal AGAVE-201 trial of axatilimab in cGVHD; updated results from Phase 1/2 trial anticipated in 4Q21 -

- Company to host conference call today at 4:30 p.m. ET –

WALTHAM, Mass., August 9, 2021 (PRNEWSWIRE) – Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq: SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today reported its financial results for the second quarter ended June 30, 2021. In addition, the Company provided a clinical and business update.

“The second quarter of 2021 was marked by significant progress advancing our pipeline of innovative therapeutics, and we are pleased to share that we have selected a go-forward dose for the pivotal Phase 2 portion of AUGMENT-101 based on favorable findings from the intermediate dose cohort,” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “Enrollment in the trial continues, with recently enrolled patients expected to count towards the Phase 2 expansion portion, subject to endorsement of the Phase 2 dose by the FDA. We are also excited to announce an important step in our plans to expand development of SNDX-5613 into earlier lines of therapy with the initiation of the first frontline combination trial of a menin inhibitor in the Leukemia & Lymphoma Society’s Beat® AML Master Clinical Trial.”
“Beyond SNDX-5613, enrollment remains on track in the ongoing global pivotal AGAVE-201 trial of axatilimab in patients with chronic graft versus host disease (cGVHD), and we continue to expect topline data from the trial in 2023. In addition, as previously announced, we anticipate sharing updated results from the recently completed Phase 1/2 trial of axatilimab in cGVHD later this year and remain committed to unlocking the full potential of axatilimab in the growing number of cGVHD patients lacking effective interventions.”

Recent Progress and Anticipated Milestones

SNDX-5613

- In May 2021, the Company reported updated data from the ongoing Phase 1 dose escalation portion of the Phase 1/2 AUGMENT-101 trial of SNDX-5613, a highly selective oral menin inhibitor, in patients with MLLr and NPM1c mutant relapsed/refractory (R/R) acute leukemias. The updated May data showed that a total of 7/31 patients (23%) have achieved CR/CRh.

  Based on positive findings from the intermediate dose cohort, in which no dose limiting toxicities were observed, the Company has selected 276 mg of SNDX-5613 every 12 hours in patients who are not receiving a concomitant strong CYP3A4 inhibitor (Arm A) and 163 mg every 12 hours for patients who are receiving a concomitant strong CYP3A4 inhibitor doses (Arm B), for Phase 2. Enrollment in the trial remains ongoing, with recently enrolled patients expected to count towards the Phase 2 expansion portion, subject to endorsement of the Phase 2 dose by the FDA.

- The Company today announced it will initiate a frontline trial of SNDX-5613 in combination with venetoclax and azacytidine in newly diagnosed acute myeloid leukemia (AML) patients unable to tolerate induction chemotherapy. The trial will be conducted as part of the Leukemia & Lymphoma Society’s Beat® AML Master Clinical Trial, a collaborative clinical trial that aims to change the paradigm of AML treatment through a precision medicine approach. SNDX-5613 is the first menin inhibitor to be included in the Beat AML Master Clinical Trial.

- The Company also announced today that it plans to initiate a new trial to assess the safety, tolerability, and preliminary anti-leukemic efficacy of SNDX-5613 in combination with chemotherapy in patients with relapsed or refractory MLLr or mNPM1 acute leukemias. The Phase 1b trial, which will be referred to as AUGMENT-102, is expected to enroll up to 27 patients.

- In June 2021, the Company announced that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation (FTD) to SNDX-5613 for the treatment of adult and pediatric patients with relapsed or refractory acute leukemias harboring a MLLr or NPM1 mutation. FTD is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fulfill an unmet medical need, enabling drugs to reach patients earlier.

Axatilimab

- In May 2021, Syndax announced that enrollment is complete in the Phase 2 expansion portion of the Phase 1/2 trial of axatilimab, its anti-CSF-1R monoclonal antibody, in patients with cGVHD. The Company continues to anticipate reporting updated results at a medical meeting in the fourth quarter of 2021 for 40 patients, including the 17 patients in the Phase 1 portion and 23 patients from the Phase 2 expansion portion, which evaluated 1 mg/kg of axatilimab every two weeks. At the American Society of Hematology Annual Meeting in December 2020, preliminary data from the Phase 1 portion of the trial were reported during an oral presentation highlighting the tolerability and high response rate of axatilimab in cGVHD patients refractory to multiple therapeutic agents.

  Enrollment is ongoing in the Company's global pivotal Phase 2 AGAVE-201 trial of axatilimab in patients with cGVHD, with topline data expected in 2023. The trial will evaluate the safety and efficacy of three doses and schedules of axatilimab. The primary endpoint will assess objective response rate based on the 2014 NIH consensus criteria for cGVHD, with key secondary endpoints including duration of response and improvement in modified Lee Symptom Scale score.

- Earlier this year, the Company announced that the U.S. FDA granted Orphan Drug Designation to axatilimab for the treatment of patients with cGVHD and idiopathic pulmonary fibrosis.

Second Quarter 2021 Financial Results

As of June 30, 2021, Syndax had cash, cash equivalents and short-term investments of $253.1 million and 51.9 million shares and share equivalents issued and outstanding. This includes 3.3 million pre-funded warrants.

Second quarter 2021 research and development expenses increased to $16.9 million from $10.9 million for the prior year period. The increase was primarily due to increased clinical trial activities and increased CMC activities.

General and administrative expenses for the second quarter 2021 decreased to $5.8 million from $6.0 million for the prior year period. The decrease is primarily due to decreased pre-commercialization expenses for entinostat partially offset by employee related expenses.

For the three months ended June 30, 2021, Syndax reported a net loss attributable to common stockholders of $22.9 million or $0.44 per share compared to $17.1 million or $0.42 per share for the prior year period.

Financial Update and Guidance

For the third quarter of 2021, research and development expenses are expected to be $25 to $30 million, and total operating expenses are expected to be $30 to $35 million. For the full year of 2021, research and development expenses are expected to be $90 to $100 million, and total operating expenses are expected to be $110 to $120 million.

Conference Call and Webcast

In connection with the earnings release, Syndax's management team will host a conference call and live audio webcast at 4:30 p.m. ET today, Monday, August 9, 2021.

The live audio webcast and accompanying slides may be accessed through the Events & Presentations page in the Investors section of the Company's website at www.syndax.com. Alternatively, the conference call may be accessed through the following:

Conference ID: 2871946
Domestic Dial-in Number: (855) 251-6663
International Dial-in Number: (281) 542-4259
Live webcast: https://edge.media-server.com/mmc/p/n7kmwwkz

For those unable to participate in the conference call or webcast, a replay will be available on the Investors section of the Company's website, www.syndax.com.

About Syndax Pharmaceuticals, Inc.

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. The Company's pipeline includes SNDX-5613, a highly selective inhibitor of the Menin–MLL binding interaction, axatilimab, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, and entinostat, a class I HDAC inhibitor. For more information, please visit www.syndax.com or follow the Company on Twitter and LinkedIn.

Syndax's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend," "believe" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Syndax's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the design, progress, timing, clinical development and scope of clinical trials, plans for initiating future clinical trials, reporting of clinical data for Syndax's product candidates, the association of data with treatment outcomes, the potential use of our product candidates to treat various cancer indications and fibrotic diseases, Syndax's expected third quarter and full year research and development expenses, and expected total operating expenses. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical trials, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, the COVID-19 pandemic may disrupt our business and that of the third parties on which we depend, including delaying or otherwise disrupting our clinical trials and preclinical studies, manufacturing and supply chain, or impairing employee productivity, failure of Syndax's collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. Other factors that may cause Syndax's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Syndax's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, Syndax assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

SYNDAX PHARMACEUTICALS, INC.
(unaudited)
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	June 30, 2021	December 31, 2020
Cash, cash equivalents and short-term investments	$ 253,132	$ 293,065
Total assets	$ 263,059	$ 300,613
Total liabilities	$ 48,496	$ 48,425
Total stockholders' equity (deficit)	$ 214,563	$ 252,188
Common stock outstanding	48,616,628	47,881,223
Common stock and common stock equivalents*	59,455,423	57,836,910
*Common stock and common stock equivalents:		
Common stock	48,616,628	47,881,223
Common stock warrants (pre-funded)	3,307,952	3,557,952
Common stock and pre-funded stock warrants	51,924,580	51,439,175
Options to purchase common stock	7,406,760	6,379,235
Restricted Stock Units	124,083	18,500
Total common stock and common stock equivalents	59,455,423	57,836,910

SYNDAX PHARMACEUTICALS, INC.
(unaudited)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
License fee revenue	$ 379	$ 379	$ 758	$ 758
Operating expenses:				
Research and development	16,871	10,943	38,742	20,505
General and administrative	5,842	6,046	11,513	11,963
Total operating expenses	22,713	16,989	50,255	32,468
Loss from operations	(22,334)	(16,610)	(49,497)	(31,710)
Other (expense) income, net	(576)	(452)	(1,136)	(588)
Net loss	$ (22,910)	$ (17,062)	$ (50,633)	$ (32,298)
Net loss attributable to common stockholders	$ (22,910)	$ (17,062)	$ (50,633)	$ (36,204)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.44)	$ (0.42)	$ (0.98)	$ (0.97)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	51,603,286	40,609,205	51,551,844	37,468,922

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